REMARKS

Claim 17 has been amended to recite "[a]n isolated polypeptide for cleaving inhibitor of apoptosis (IAP), which consists essentially of variant Omi (SEQ ID NO. 45)." Support for this amendment is found in original claim 17 and in the specification at, for example, paragraph 61 and in the sequence listing as originally filed. *See In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01 (o) and (l).

Claim 18 has been amended to recite a composition comprising the polypeptide of claim 17 and a pharmacologically acceptable carrier. Support for this amendment is found in original claim 18 and in the specification at, for example, paragraph 26. (*Id.*).

It is submitted that no new matter has been introduced by the foregoing amendment. Approval and entry of the amendment is respectfully solicited.

Specification Objections:

The Examiner objected to the specification for various informalities. (Paper No. 20070326 at 2-3). The Examiner asserted that the use of trademarks should be capitalized and "accompanied by the generic terminology." (*Id.* at 2). The Examiner further asserted that "[t]he title of the invention is not descriptive," and that the brief description of Figures 1-6 should be amended. (*Id.*).

With a view towards furthering prosecution, the specification has been amended to correct, *inter alia*, the informalities noted above by the Examiner. No new matter has been introduced by the amendments. Approval and entry of the amendments respectfully is requested.

The Examiner also asserted that "[t]he sequence notation throughout the specification is improper, see for example page 16, 'SEQ ID NO. 44' which should be 'SEQ ID NO: 44.'" (*Id.* at 3).

We note that the Examiner is mistaken. The use of the citation format "SEQ ID NO." to identify sequence listings is a proper citation format. It is both clear and an acceptable form of citing sequences. The MPEP even acknowledges it as a means of sequence citation. *See* MPEP § 2422.03 at 2400-34 (8th Ed., Rev. 5, August 2006) ("37 CFR 1.821(c) requires that each sequence disclosed in the application appear separately in the 'Sequence Listing,' ***with each sequence further being assigned a sequence identification number, referred to as 'SEQ ID NO:'***") (emphasis added). Indeed, a search of the USPTO's issued patent database reveals hundreds, if not thousands, of patents that have issued using this citation format.[1] There have been at least two patents this past month that have issued using this citation format. *See, e.g.*, U.S. Patent Nos. 7,238,479 and 7,238,359. Even the Examiner has allowed patents to issue using this citation format. *See, e.g.*, U.S. Patent Nos. 6,635,447, 6,458,927, and 6,489,454. Thus, for the reasons set forth above, it is respectfully submitted that this objection should be withdrawn.

In view of the foregoing, it is respectfully submitted that the specification objections have been rendered moot and should be withdrawn.

[1] A search of the USPTO's issued patent database using the search term "SEQ ID NO." revealed 44,373 hits. However, these hits appear to include issued patents that use the citation format "SEQ ID NO." and/or "SEQ ID NO:".

Sequence Compliance Objections:

The Examiner objected to the specification because "[t]he specification discloses sequences that have not been identified by a sequence identifier, see for example, page 14: Fig. 5B 'ASQRLFPG' ... and 'AVPS'; ...." (Paper No. 20070326 at 4).

With a view towards furthering prosecution, the specification has been amended to correct, *inter alia*, the informalities noted above by the Examiner. No new matter has been introduced by the amendments. Approval and entry of the amendments respectfully is requested.

The specification has also been amended to replace the Sequence Listing as previously filed with the substitute Sequence Listing attached hereto as Exhibit A. Support for this amendment is found in the Sequence Listing as previously filed and the specification at, for example, paragraphs [0011] and [0049]. Also attached hereto as Exhibit B is a computer readable form ("CRF") of the Sequence Listing.

Pursuant to 37 CFR. § 1.821(f), undersigned counsel hereby represents that, upon information and belief, the content of the paper copy and CRF of the Sequence Listing enclosed herewith are the same, and no new matter has been added. Entry of the Sequence Listing is respectfully solicited.

The Examiner also asserted that at "page 15: Fig. 7C 'DEVD,' (and throughout the specification)" there is no sequence identifier for this sequence. (*Id.*).

We note that the Examiner is mistaken. The reference to "DEVD" in the specification refers to a specific polypeptide *activity*, not to an amino acid sequence *per se* requiring a sequence identifier. *See, e.g.,* Specification at paragraph [0254] ("DEVD

relates to a fluorogenis substrate used to measure activity of caspase."). Thus, because the reference to "DEVD" does not require a sequence identifier, it is respectfully submitted that this objection should be withdrawn.

In view of the foregoing, it is respectfully submitted that the sequence compliance objections have been rendered moot and should be withdrawn.

Claim Objection:

The Examiner objected to claim 17 allegedly because the claim recites non-elected subject matter and for the recitation of the acronym "IAP." (Paper No. 20070326 at 5). With respect to the Examiner's contention that claim 17 recites "non-elected subject matter," we note that the Examiner ignored the October 5, 2006 Response To Restriction Requirement requesting reconsideration of the election of species requirement. We respectfully submit that examining the small group of related sequences recited in claim 17 is not over-burdensome. And, requiring the Applicants to limit claim 17 to a single sequence is unduly restrictive.

Notwithstanding the foregoing and with a view toward furthering prosecution, claim 17 has been amended to recite SEQ ID NO:45. Cancellation of the so-called non-elected subject matter is without prejudice.

With respect to the Examiner's objection to the use of the "IAP" acronym, claim 17 has been amended to "spell out" the acronym.

In view of the foregoing, it is respectfully submitted that the objections to claim 17 have been rendered moot, and should be withdrawn.

Rejection Under 35 USC § 101:

Claims 17-19 and 87 have been rejected under 35 USC §101 as directed to non-statutory subject matter. (Paper No. 20070326 at 5). In making the rejection, the Examiner asserted that claim 17 "reads on a product of nature." (*Id.*).

With a view towards furthering prosecution, claim 17 has been amended to recite "[a]n isolated polypeptide ..." as requested by the Examiner. (*Id.*). Accordingly, this rejection has been rendered moot, and should be withdrawn.

Rejections Under 35 USC § 112, Second Paragraph:

Claims 17-19 and 87 were rejected under 35 USC §112, second paragraph for various reasons. (Paper No. 20070326 at 6).

With respect to claim 18, the Examiner alleges that the recitation of "the polypeptide of claim 17" and "a pharmacologically acceptable carrier" are "unclear." (*Id.*). Initially, we note that claim 17 has been amended to recite SEQ ID NO:45. Thus, the Examiner's concern with respect to which polypeptide is referred to in claim 18 has been rendered moot. We further note that claim 18 has been amended to recite "a composition." Accordingly, the Examiner's concern with respect to antecedent basis between claims 17 and 18 has been rendered moot.

With respect to the Examiner's comments regarding claims 2-4 and claim 17, we respectfully submit that they are misplaced. For example, the Examiner asserts that "it is unclear what sequence has position S53N (claim 3)." (*Id.*). The Examiner also asserts that "claims 2-4 are indefinite because the claims recite positions not found in SEQ ID NO:11." Further, the Examiner asserts that "[c]laim 17 is indefinite for the recitation of 'Figure 1' ...." (*Id.*).

For the reasons set forth below, these rejections are traversed.

Initially, we note that claims 2-4 have been withdrawn previously by the Examiner as drawn to non-elected subject. (Paper No. 20070326 at 2). If the Examiner has reconsidered the restriction requirement, we respectfully request that she advise us in writing. We also note that claims 2-4 do not recite a sequence having position "S53N," nor do claims 2-4 recite "SEQ ID NO:11," nor does claim 17 recite "Figure 1." We suspect that this rejection belongs in another case.[2/] Thus, because the rejections of claims 2-4 and 17 do not appear to be related to the presently claimed subject matter, these rejections are irrelevant and should be withdrawn.

Rejection Under 35 USC § 102(b):

Claims 17-19 have been rejected under 35 USC §102(b) as anticipated by Karran *et al.*, EP Publication No. 0 828 003 A2 ("Karran"). For the reasons set forth below, the rejection is respectfully traversed.

Karran discloses "isolated human serine protease (PSP1) polynucleotides, their homologs and isoforms and polymorphic variants ...." (p. 2, lines 1-5). Karran further discloses at least 40 different SEQ ID numbers.

In making the rejection, the Examiner asserted only that "[t]he reference teaches a protein structure that is 99.9% identical to the claimed SEQ ID NO:45 (variant Omi), see the alignment. Therefore, the limitations of the claims are met by the reference." (Paper No. 20070326 at 7).

As is well settled, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply,* 33 USPQ2d 1496, 1498 (Fed. Cir.

[2/] Indeed, we found the identical rejection in Paper No. 20070324 (pp. 11-12) of USSN 11/294,670.

1995). Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir 1984). Furthermore, in a §102(b) rejection there must be no difference between what is claimed and what is disclosed in the applied reference. *In re Kalm*, 154 USPQ 10, 12 (CCPA 1967); *Scripps v. Genentech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). "Moreover, it is incumbent upon the Examiner to ***identify wherein each and every facet*** of the claimed invention is disclosed in the applied reference." *Ex parte Levy*, 17 USPQ2d 1461, 1462 (BPAI 1990). The Examiner is required to point to the disclosure in the reference "***by page and line***" upon which the claim allegedly reads. *Chiong v. Roland*, 17 USPQ2d 1541, 1543 (BPAI 1990).

Initially, we note that the language of the rejection confirms that Karran is not anticipatory. It is respectfully submitted that "99.9%," even if accepted as true, is not "identity." Thus, for this reason alone the rejection is deficient as a matter of fact and law and should be withdrawn.

We further note that the rejection fails to identify, which sequence, among the many disclosed by Karran, is being used by the Examiner as the basis for the rejection. As set forth in *Chiong supra*, the Examiner is required to specifically identify the disclosure upon which the claim allegedly reads. This the Examiner has not done. For this reason also, the rejection is deficient and should be withdrawn.

We further note, that claim 17 has been amended to recite "[a]n isolated polypeptide for cleaving inhibitor of apoptosis (IAP), which consists essentially of variant Omi (SEQ ID NO. 45)." We respectfully submit that the rejection does not - and cannot

- identify wherein Karran such an isolated polypeptide is disclosed. In this regard, we also observe that the rejection is completely silent as to the elements recited in claims 18 and 19. The rejection makes no attempt to identify wherein Karran is disclosed the composition recited in amended claim 18 or the polypeptide recited in claim 19. For these reasons as well the rejection is deficient and should be withdrawn.

For the reasons set forth above, entry of the amendments, withdrawal of all objections and rejections, and allowance of all claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on August 13, 2007.

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Respectfully submitted,

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